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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,510	01/23/2004	Michael J. Dalton	9250/3	7231

7590 12/30/2005

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EXAMINER
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MENDEZ, MANUEL A

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 12/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/763,510	Applicant(s) DALTON, MICHAEL J.	
	Examiner Manuel Mendez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 September 2005 and 23 May 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2, 4-8 and 15-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-8 and 15-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

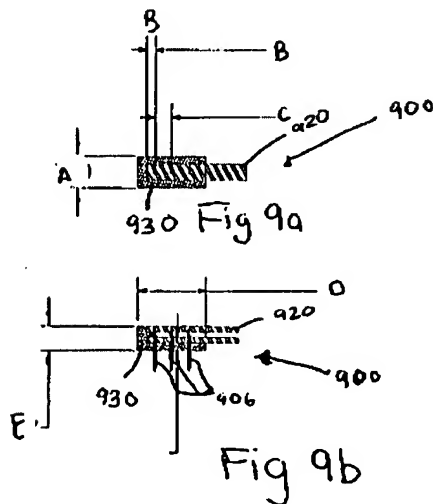
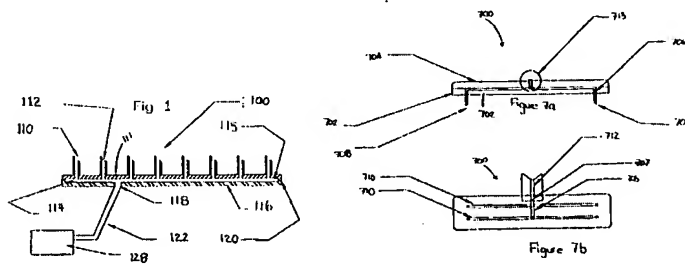
- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION*****Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

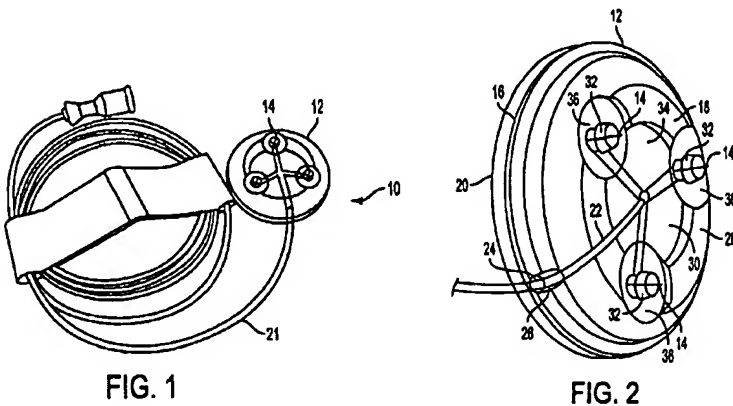
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 1 and 18, 5-8, 15, 21-24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over [Douglas or Lastovich, et al.], in view of Connelly, et al., and in further view of Fleming, et al., or Cirelli, et al.**



Art Unit: 3763

In figures 1, 7a, 7b, 9a, and 9b (above), the Douglas patent shows a delivery tube including a central lumen, a first end and a second end, a support base attached adjacent a first end of the delivery tube, and a plurality of needles extending substantially perpendicular to the support base and in communication with the central lumen of the delivery tube.

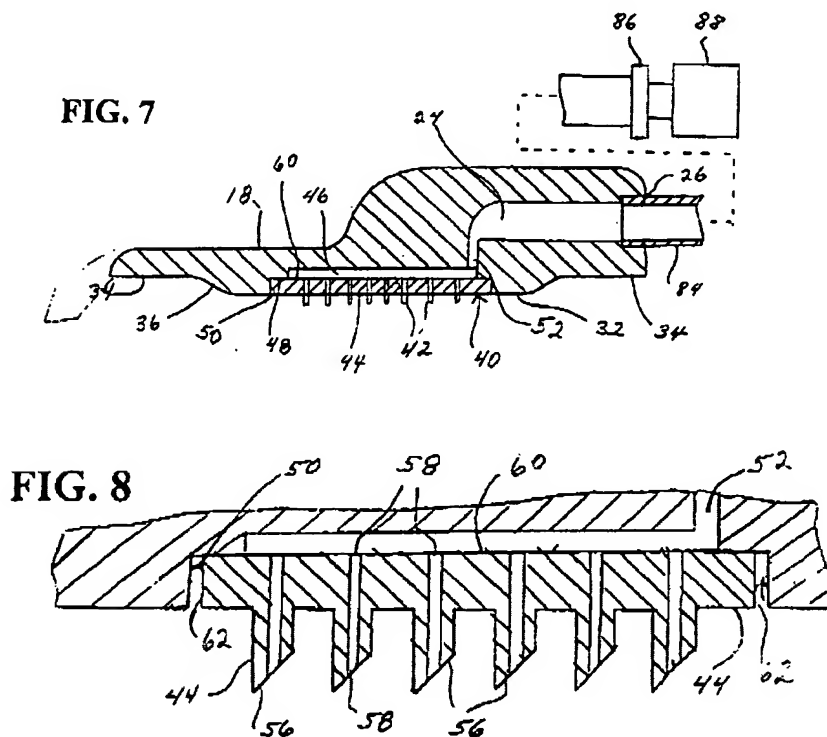


In figures 1 and 2, the Lastovich, et al., patent shows a delivery tube including a central lumen, a first end and a second end, a support base attached adjacent a first end of the delivery tube, and a plurality of needles extending substantially perpendicular to the support base and in communication with the central lumen of the delivery tube.

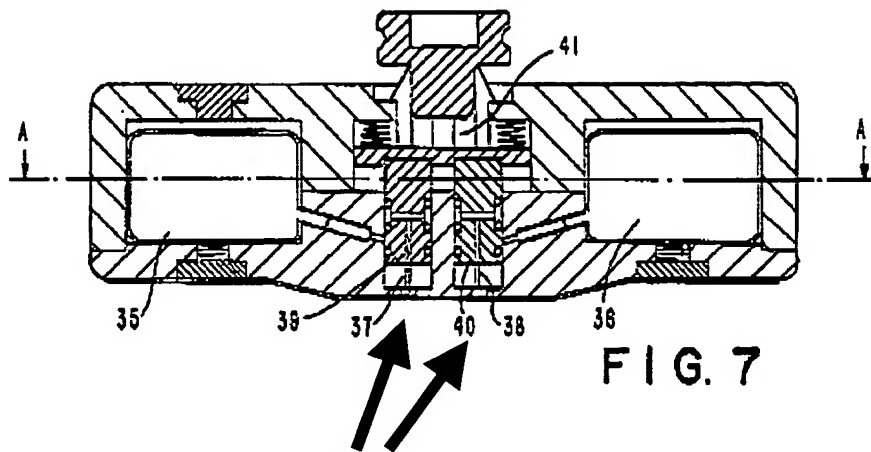
In the remarks section of the amendment, the applicant alleges that the patents discussed above do not disclose a flexible delivery tube including a central lumen, a closed first end and an open second end and a flexible planar support base attached adjacent the first end of the delivery tube, the support base having a plurality of openings, each of the plurality of openings for receiving one of the plurality of needles.

Art Unit: 3763

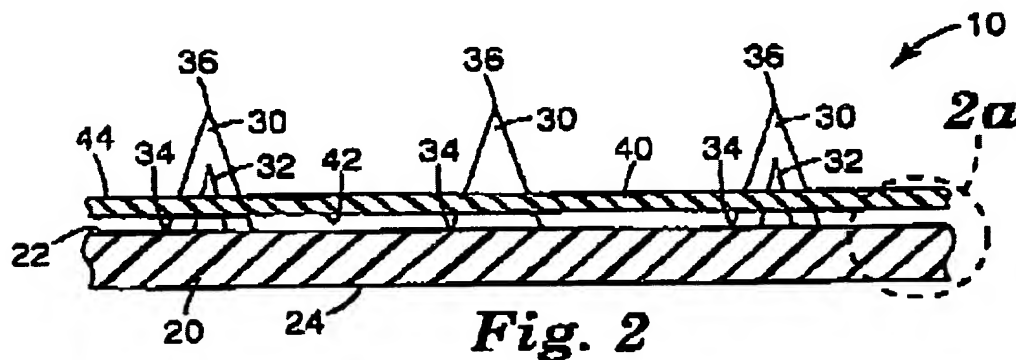
However, these enhancements are conventional in the art as evidenced by the teachings of Connelly, et al., Cirelli, et al., or Fleming, et al.



In figures 7 and 8 (above), Connelly, et al., shows a central lumen (24), a closed first end (60) and an open second end (52), and a flexible planar support base (44) attached adjacent the first end of the delivery tube. Connelly, et al., does not disclose a base having a plurality of openings for receiving the needles. However, such "base design" is conventional in the art as evidenced by the teachings of Cirelli, et al., or Fleming, et al.



The Cirelli, et al., patent shows in figure 7, a base having apertures that receive needles (37, 38) as they are inserted into the skin.



Similarly, Fleming, et al., shows in figure 2, a "base design" wherein the base (44) receives needles (36) as the needles protrude said base.

Based on the above observations and in response to applicant's comments, the modification of the apparatuses disclosed by Douglas or Lastovich, et al., with a central lumen having a closed first end and an open second end as taught by Connelly, et al., and furthermore, with a support base having a plurality of openings, each of the plurality of openings for receiving one of the plurality of needles, as taught by Cirelli, et al., or Fleming, et al., would have been considered obvious in view of the conventionality of

Art Unit: 3763

these enhancements. Additionally, these enhancements would have increased the accuracy of the injection mechanism resulting in a safer medical environment.

In relation to **claims 5 and 21**, Douglas demonstrates the conventionality of using adhesive to attach infusion systems to the skin; in relation to **claim 6 and 22**, Douglas discloses an apparatus wherein needles are in communication with the central lumen; in relation to **claims 7, 8, 23, and 26**, Douglas also demonstrates the conventionality of infusion systems having needles in parallel and in series, and finally, in relation to **claims 15 and 24**, Lastovich, et al., demonstrates the conventionality of using support bases having a circular shape.

**Claims 2 and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over [Douglas or Lastovich, et al.], in view of Connelly, et al., or Fleming, et al., or Cirelli, et al., as discussed above, and in further view of Bierman, et al.

None of the references discussed above appears to disclose the use of a luer fitting. However, the use of luer fittings in combination with infusion systems is conventional in the art as evidenced by Bierman, et al. This patent shows in figure 1, the use of a luer fitting to facilitate the connection between a container and an infusion needle.

Based on the above observations, for a person of ordinary skill in the art, it would have been considered obvious to modify any of the infusion systems disclosed above, with luer fittings to facilitate the steps of connecting and disconnecting supply lines as taught Bierman, et al. Additionally, such enhancement would have improved the efficiency of the infusion system, resulting in a safer operational environment.

Art Unit: 3763

**Claims 4 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over [Douglas or Lastovich, et al.], in view of Connelly, et al., or Fleming, et al., or Cirelli, et al., as discussed above, and in further view of Goldowsky.

None of the references discussed above appears to expressly disclose the infusion rates of approximately 120 to 200 cc/hr. However, such infusion rates are conventional in the art as evidenced by Goldowsky. The Goldowsky patent teaches the infusion of substances at infusion rates of approximately 120 to 200 cc/hr.

Based on the above observations, for a person of ordinary skill in the art, modifying any of the infusion systems disclosed above with infusion rates of 120 to 200 cc/hr would have been considered obvious in view of the conventionality of these particular infusion rates.

**Claims 16, 17, 25, and 27** are rejected under 35 U.S.C. 103(a) as being unpatentable over [Douglas or Lastovich, et al.], in view of Connelly, et al., or Fleming, et al., or Cirelli, et al., as discussed above, and in further view of Hazel, et al.

None of the references discussed above discloses the use of a triangular base. However, triangular bases are conventional in the art as evidenced by the teachings of Hazel, et al. The Hazel, et al., patent discloses a triangular base to attach medical equipment to the skin.

Based on the above observations, modifying any of the bases of the infusions systems discussed above, with a triangular base as taught by Hazel, et al., would have been considered obvious in view of the conventionality of this enhancement.



***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

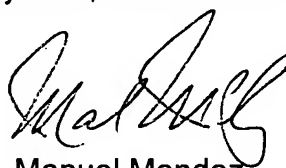
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel Mendez whose telephone number is 703-272-4977. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Manuel Mendez  
Primary Examiner  
Art Unit 3763

MM